

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Methyl Salicylate Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients % w/w

Methyl salicylate 45%

Ointment Base 55%

3 PHARMACEUTICAL FORM

Ointment.

4 CLINICAL PARTICULARS

Therapeutic Indications

For the relief of pain in Lumbago sciatica and rheumatic conditions

In the local management of the symptoms of fibrositis, muscle strains and arthroses.

Posology and method of administration

Topical to the affected area. Massage into affected part until absorbed. Repeat several times daily for continued relief. This product should not be applied to neonates, infants or children under 16 years of age.

Contraindications

Not to be applied to mucous membranes or broken skin or children under 16 years of age.

Special warnings and precautions for use

For external use only.

Wash hands thoroughly after applying. Avoid contact with the eyes, broken skin or mucous membranes. If the condition is aggravated or there is no improvement, consult the doctor.

Interaction with other medicinal products and other forms of interaction

No interactions observed or reported with this product.

Fertility, pregnancy and lactation

There is no evidence of contra-indication in pregnancy or lactation.

Effects on ability to drive and use machines

None known.

Undesirable effects

Menthol may give rise to hypersensitivity reactions including contact dermatitis. In the event of an allergic reaction, the product should be washed off the skin with soap and water.

Post-marketing Data:

Adverse drug reactions (ADRs) identified during post-marketing experience with methyl salicylate / Levomenthol are included in table below. The frequencies are provided according to the following convention: Very common (1/10); Common (1/100 and < 1/10); Uncommon (1/1,000 and < 1/100); Rare (1/10,000, <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

Body System (SOC)	Frequency	Adverse Drug Reaction
Skin and Subcutaneous Tissue Disorders	Not known	Burns at application site

Overdose

No information.

5 PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Counter irritant.

Mild local rubefacient and anodyne action.

Pharmacokinetic properties

(a) General characteristics

While local absorption of the active ingredients may occur, the amount applied relative to the total body mass is small. Thus, systemic pharmacological activity is unlikely and the action of the product is restricted to its local action.

(b) Characteristics in patients

No information available.

Preclinical safety data

No information.

6. Incompatibilities

Not applicable.

Shelf life

3 years.

Special precautions for storage

Do not store above 25°C. Keep the cap tightly closed. Store in the original carton in order to protect from light.

Nature and contents of container

125ml polyethylene terphthalate (PET) clear bottle with cap.

Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

6 PHARMACEUTICAL PARTICULARS

List of excipients

Liquid paraffin
Cetostearyl alcohol
Sodium laurilsulfate (E487)
Sunset yellow (E110) Purified
water

7 MARKETING AUTHORISATION HOLDER

Nino Pharm & Chem Co. Ltd
1, Nino Crescent Era Town,
Off Badagry Expressway,
Ojo LGA Lagos.

8 MARKETING AUTHORISATION NUMBER

04-4747

